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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/889,793 | 10/24/2001 | Robert Johan Joseph Hageman | BO 42384 | 8792 |

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| EXAMINER | |
|---|---|
| KHARE, DEVESH | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1623 | |

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/889,793 | HAGEMAN ET AL. | |
| | Examiner | Art Unit | |
| | Devesh Khare | 1623 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 16-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 16-30 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

***35 U.S.C. 112, first paragraph rejection***

***Claims 16-30*** are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Many of the factors regarding undue experimentation have been summarized in *In re Wands,* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);

(2) The amount of direction or guidance presented;

(3) The presence or absence of working examples of the invention;

(4) The nature of the invention;

(5) The state of the prior art;

(6) The relative skill of those in the art;

(7) The predictability or unpredictability of the art; and

(8) The breadth of the claims.

The applicant's specification fails to provide sufficient guidance or support to enable the worker of ordinary skill in the art to practice methods for preventing serotonin- or melatonin-mediated disorders by the administration of an effective amount of a combination of folic acid, vitamin B6 and B12 and at least one component selected from the group consisting of riboflavin, thiamin, niacin and zinc. The specification describes the alleged prevention of serotonin- or melatonin-mediated disorders in a prophetic manner only. Such allegations are not considered to provide sufficient support for presuming or establishing methodological procedures for preventing serotonin- or melatonin-mediated disorders, particularly since there is not seen sufficient guidance and support in the specification or correlation of that which is disclosed with prior art teachings to support same.

Further, there is no enabling description of the administration of an effective amount of a combination of folic acid, vitamin B6 and B12 and atleast one component selected from the group consisting of riboflavin, thiamin, niacin and zinc for preventing serotonin- or melatonin-mediated disorders. The worker of ordinary skill in the art would not be able to practice the instantly claimed method given the limited guidance provided by the disclosure herein. The mere statements that the compounds of the instant invention are likely to be effective, or expected to be effective on the basis of limited *in vitro* test data, are insufficient to enable the worker of ordinary skill in the art to practice the invention commensurate in scope with these claims. It is well known and established that the "law requires that disclosure in an application shall inform those skilled in the art how to use

appellant's alleged discovery, not how to find out how to use it for themselves." *In re Gardner et al.,* 166 USPQ 138(CCPA 1970).

***35 U.S.C. 112, second paragraph rejection***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

Claims 16-30 is rejected under the second paragraph of 35 U.S.C. 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 16 and 29, the phrase "such as" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). The term also renders claims depending from 16 and 29 indefinite (see claims 17-28 and 30).

The phrase "improving senses of well being, control of feeling of pain and improvement of mood and sleeping behavior" in claims 16 and 29 is a relative phrase, which renders the claim indefinite. The phrase "improving senses of well being, control of feeling of pain and improvement of mood and sleeping behavior" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 16 sets forth-improper markush terminology. The language " at least one component selected from" at line 7 should be changed to –at least one component selected from the group consisting of--.

Claim 24-lack antecedent basis for the phrase "weight ratio of magnesium plus zinc to calcium" (i.e. it has not been established that this phrase is related to claim 17).

Claims 29 and 30 set forth-improper Markush terminology. The term "at least one of" should be changed to –at least one of the group consisting of--.

Claims 20-25 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "per 100 kcal" is unclear. It is unclear which components deliver said 100 kcal in the claimed compositions. Claims which depend from an indefinite claim which fail to obviate the indefiniteness of the claim from which they depend are also seen to be indefinite and are also rejected for the reasons set forth supra.

**35 U.S.C. 103(a) rejection**

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

**Claims 16-28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Serfontein (U.S. Patent 5,631,271) in view of Paul et al. (U.S. Patent 5,292,538).

Claims 16-28 are drawn to method for the treating serotonin- or melatonin-mediated disorders with folic acid, vitamin B6 and B12 and at least one component selected from the groups consisting of riboflavin, thiamine, niacin and zinc, wherein folic acid is more than 44 µg, vitamin B12 more than 0.8 µg, vitamin B6 more than 50 µg and atleast 0.55 mg of niacin and/or at least 0.08 mg of riboflavin and/or at least 55 µg of thiamine, with further comprising carbohydrates, fats and proteins.

Serfontein teaches a composition comprising vitamin B6, folate and vitamin B12, for treatment and prophylaxis of metabolic disturbances in infants (see abstract). Serfontein disclosed a substance or composition for use in a method to enhance or stimulate the immune response system of human and animal by enhancing their methylation capacity (see col. 1, lines 6-12). Serfontein disclosed a pharmaceutical composition in col. 10, lines 38-62, that is essentially a combination of vitamin B6, folate and vitamin B12. Serfontein also suggest in col. 12, lines 1-10, the daily dosages of ingredients in an infant food formula in the ranges of vitamin B6 (0.01-5 mg), riboflavin (0.01-5 mg), folate (.001-0.5 mg) and vitamin B12 (0.01-10 µg ). Furthermore, under Example 10 in col. 31, an infant food formula is disclosed, wherein the protein (1.6%), fat (3.3%) and carbohydrate (67.0%) with vitamin and minerals containing 0.5 mg of folic acid, 0.17 mg of B12, 0.2 mg of zinc, 10 mg of calcium, 5 mg of magnesium and 1.0 mg of niacin is provided in a composition to treat premature infants. Serfontein differs from the applicant's invention that Serfontein does not provide an explicit example of a nutritional

composition, comprising the tryptophan and/or melatonin and/or adenosine, however Serfontein does provide motivation to use vitamin B6, riboflavin, folate, vitamin B12 and protein, fat and carbohydrate, for treatment and prophylaxis of metabolic disturbances in infants. Use of a known member of a class of materials in a process is not patentable if other members of the class were known to be useful for that purpose, even though results are better than expected.

Paul et al. teach a method of providing sustained energy and nutrition for anabolic physiological state in a human by administering to said human a nutritional composition containing carbohydrates, lipids, protein and magnesium in the form of amino acid chelate and other vitamins and nutrients (see abstract). Paul et al. disclose a composition under Example in cols. 10 and 11, containing the said ingredients for use to support an anabolic physiological state in humans. It is noted that Paul et al. does not provide specific disclosures regarding the treatment of serotonin- or melatonin-mediated disorders.

Therefore, one of ordinary skill in the art would have found the applicants claimed method for the treating of serotonin- or melatonin-mediated disorders with a pharmaceutical composition containing folic acid, vitamin B12, vitamin B6, and further containing at least one group consisting of riboflavin, thiamin, niacin and zinc, to have been obvious at the time the invention was made having the above cited references before him. Since Serfontein teaches a composition comprising the pyridoxal in combination of folic acid, vitamin B6 and B12 for the treatment of depressed or inadequate intracellular pyridoxal phosphate levels in a human or animal and Paul et al.

teach a method of providing sustained energy and nutrition for anabolic physiological state in a human by administering to said human a nutritional composition containing carbohydrates, lipids, protein and magnesium in the form of amino acid chelate and other vitamins and nutrients, one skilled in the art would have a reasonable expectation for success in combining both references to accomplish a pharmaceutical composition for the treatment for serotonin- or melatonin-mediated disorders.

**Claims 29 and 30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Serfontein (U.S. Patent 5,631,271).

Claims 29 and 30 are drawn to a pharmaceutical composition for treatment of serotonin- or melatonin-mediated disorders, containing more than 44 µg of folic acid, more than 0.8 µg of vitamin B12, more than 50 µg of vitamin B6, and further containing at least one group consisting of riboflavin, thiamin, niacin and zinc.

Serfontein discloses a pharmaceutical composition in col. 10, lines 38-62, that is essentially a combination of vitamin B6, folate and vitamin B12. Serfontein also suggests in col. 12, lines 1-10, the daily dosages of ingredients in an infant food formula in the ranges of vitamin B6 (0.01-5 mg), riboflavin (0.01-5 mg), folate (.001-0.5 mg) and vitamin B12 (0.01-10 µg ). Serfontein differs from the applicant's invention that Serfontein does not provide an explicit example of a nutritional composition for the treatment of serotonin- or melatonin-mediated disorders which comprises thiamin, however Serfontein does provide motivation to use vitamin B6, riboflavin, folate, vitamin B12 in a pharmaceutical composition. Use of a known member of a class of materials in

a process is not patentable if other members of the class were known to be useful for that purpose, even though results are better than expected.

Therefore, one of ordinary skill in the art would have found the applicants claimed pharmaceutical composition containing folic acid, vitamin B12, vitamin B6 and further containing at least one group consisting of riboflavin, thiamin, niacin and zinc, wherein folic acid is more than 44 µg, vitamin B12 is more than 0.8 µg and vitamin B6 is more than 50 µg, to have been obvious at the time the invention was made having the above reference before him because Serfontein teaches a composition comprising vitamin B6, folate and vitamin B12, for treatment and prophylaxis of metabolic disturbances in infants.

***State of the Art References***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Green et al. (U.S. Patent 5,792,754)- discloses a nutritional composition containing carbohydrates, fats and proteins.

Hageman et al. (U.S. Patent 6,420,342)- discloses nutritional preparation containing ribose, folic acid and vitamin B6.

Bell et al. (U.S. Patent Application Publication US 2002/0147153)- discloses a nutritional supplement to alleviate symptoms associated with reduced levels of serotonin.

Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is (703)605-

1199. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 703-308-4624. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Devesh Khare, Ph.D.,JD(3Y).
Art Unit 1623
January 23,2003